

K122886
p1/2

510(k) Summary

NexStat® Plus Topical Hemostat Powder NexFoam® Plus Topical Hemostat Sponge

Date Prepared: September 19, 2012

NOV 15 2012

Submitter: Hemostasis, LLC
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St. Paul, MN 55110
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Marketed Device: NexStat® Topical Hemostat Powder
NexFoam® Topical Hemostat Sponge

510(k) Clearance: K102459

Proprietary Name

Modified Device: NexStat® Plus Topical Hemostat Powder
NexFoam® Plus Topical Hemostat Sponge

Common/Usual Name: Topical hemostatic particles and foam

Classification Name: Dressing, Unclassified
Product Code – FRO General and Plastic Surgery

Establishment Registration Number: 3007225047

Description:

The Hemostasis NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge are sterile, topical wound dressings comprised of plant based polysaccharides. The hemostatic particles and foam quickly dehydrate blood cells, resulting in hemoconcentration of platelets, serum proteins and fibrinogen, leading to clotting that limits and controls bleeding.

The NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge are identical to the NexStat® Topical Hemostat Powder and NexFoam® Topical Hemostat Sponge

cleared for market under 510(k) K102459, with the exception of the cross-linking manufacturing process. The cross-linking process for the manufacture of polysaccharide hemostatic particles is being changed for the NexStat® Plus and NexFoam® Plus devices. The new cross linking process utilizes the identical cross linker used in the predicate Medafor MPH® product subject of K033666. All other materials and processes remain the same as NexStat® and NexFoam®. The indications for use remain the same as NexStat® and NexFoam®.

Indications for Use:

NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge are intended for use under the care of a health care professional as a topical dressing for the temporary treatment of moderate to severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), cuts and lacerations and for the treatment of mild bleeding from topical ENT surgical wounds and nosebleeds. It is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

Substantial Equivalence:

The NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge are substantially equivalent to the following predicate devices:

- NexStat® Topical Hemostat Powder and NexFoam® Topical Hemostat Sponge K102459
- Medafor HemaDerm™ MPH® K033666

Biocompatibility:

Biocompatibility testing was performed using the guidelines of ISO 10993 – Biological Evaluation of Medical Devices and FDA guidance document Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1). The NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge passed biocompatibility requirements for their intended use.

Sterilization:

The NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge are sterilized using a validated gamma radiation method similar to NexStat® and NexFoam® to assure a sterility assurance level (SAL) of 10^{-6} .

Bench Testing:

Design verification testing was performed on NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge to demonstrate physical and functional requirements were met.

Conclusion:

Through the data and information presented, Hemostasis, LLC considers the NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge substantially equivalent to the predicate devices already on the market (cleared by the 510(k) process) in terms of indications for use, scientific technology, design and functional performance and present no new concerns about safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Hemostatis, LLC
% Mr. Bernard Horwath
Regulatory Consultant
4486 Timberline Court
Vadnais Heights, Minnesota 55127

November 15, 2012

Re: K122886

Trade/Device Name: NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge

Regulatory Class: Unclassified

Product Code: FRO

Dated: October 16, 2012

Received: October 17, 2012

Dear Mr. Horwath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K122886

NexStat® Plus Topical Hemostat Powder and NexFoam® Plus Topical Hemostat Sponge:

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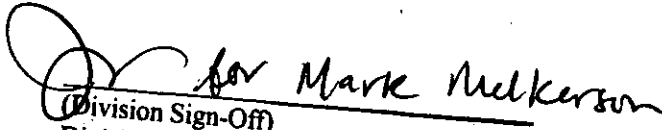
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical Devices
510(k) Number K122886